Notice of Allowability	Application No.	Applicant(s)	
	09/724,953	SCHENK, DALE B.	
	Examiner	Art Unit	
	Christopher Nichols, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *29 December 2003*.

2. ☒ The allowed claim(s) is/are *11,14,21-25,59,60,64-68 and 70-117*.

3. ☒ The drawings filed on *28 May 2003* are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. **As a courtesy to Applicant and upon review of the amendments that have obviated or rendered moot certain rejections, finality is withdrawn and prosecution on the merits is hereby reopened.**

2. The Amendment and Response filed 29 December 2003 has been received and entered in full. Claims 1-10, 12, 13, 15, 17, 20, and 26-57 have been cancelled. Claims 59-71 have been added. Claims 11 and 58 have been amended. Claims 11, 14, 16, 18, 19, 21-25, and 58-71 are under examination.

3. All Rejections and Objections not herein maintained are hereby *withdrawn* or *moot* do to amendments.

4. The Terminal Disclaimer filed 11 February 2004 has been received and entered in full.

EXAMINER'S AMENDMENT

5. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

In the Title:

METHODS OF TREATMENT OF ALZHEIMER'S DISEASE

In the Claims:

Claims 1-10 (Cancelled)

Claim 11 (Currently Amended) A method of treating ~~a disorder characterized by amyloid deposition of Aβ peptide~~ Alzheimer's disease in a mammalian subject, comprising administering to the subject a dosage of: ~~an agent~~ (a) an immunogenic Aβ fragment effective to produce an immune response comprising antibodies against ~~an amyloid component characteristic of said disorder, wherein the amyloid component is~~ Aβ; and, (b) an adjuvant that augments the immune response to ~~the~~ Aβ, ~~and~~ thereby treating ~~the disorder~~ Alzheimer's disease.

Claims 12-13 (Cancelled)

Claim 14 (Currently Amended) The method of claim 11, wherein said ~~agent~~ Aβ fragment induces an immune response directed against a neoepitope formed by ~~said~~ amyloid deposits ~~component~~ with respect to amyloid precursor protein (APP).

Claim 15-20 (Cancelled)

Claim 21 (Previously Presented) The method of claim 11, wherein said adjuvant is selected from the group consisting of STIMULON QS21, 3 De-O-acylated-monophosphoryl lipid A, and alum.

Claim 22 (Currently Amended) The method of claim 11, wherein said immune response is characterized by a serum titer of the antibodies of at least 1:1000 with respect to ~~said amyloid component~~ Aβ.

Claim 23 (Currently Amended) The method of claim 22, wherein said serum titer of the antibodies is at least 1:5000 with respect to Aβ ~~fibril component~~.

Claim 24 (Currently Amended) The method of claim 11, wherein said immune response is characterized by a serum titer of the antibodies to ~~the amyloid component~~ Aβ corresponding to greater than about four times higher than a serum titer of anti-Aβ antibodies measured in a pre-treatment control serum sample.

Claim 25 (Previously Presented) The method of claim 24, wherein said serum titer of the antibodies is measured at a serum dilution of about 1:100.

Claims 26-58 (Cancelled)

Claim 59 (Currently Amended) A method of prophylaxis ~~a disorder characterized by amyloid deposition of Aβ peptide~~ of Alzheimer's disease in a mammalian subject, comprising administering to the subject a dosage of: ~~an agent~~ (a) an immunogenic Aβ fragment effective to produce an immune response comprising antibodies against ~~an amyloid component characteristic of said disorder, wherein the amyloid component is~~ Aβ and, (b) an adjuvant that augments the

immune response to ~~the~~ Aβ, ~~and~~ thereby effecting prophylaxis of ~~the disorder~~ Alzheimer's disease.

Claim 60 (Currently Amended) The method of claim 59, wherein said ~~agent~~ Aβ fragment induces an immune response directed against a neoepitope formed by ~~said~~ amyloid deposits ~~component~~ with respect to amyloid precursor protein (APP).

Claims 61-63 (Cancelled)

Claim 64 (Previously Presented) The method of claim 59, wherein said adjuvant is selected from the group consisting of STIMULON QS21, 3 De-O-acylated-monophosphoryl lipid A, and alum.

Claim 65 (Currently Amended) The method of claim 59, wherein said immune response is characterized by a serum titer of the anti-Aβ antibodies of at least 1:1000 with respect to ~~said amyloid component~~ Aβ.

Claim 66 (Currently Amended) The method of claim 65, wherein said serum titer of the antibodies is at least 1:5000 with respect to Aβ ~~fibril component~~.

Claim 67 (Currently Amended) The method of claim 59, wherein said immune response is characterized by a serum titer of the anti-Aβ antibodies corresponding to greater than about four

times higher than a serum titer of the anti-Aβ antibodies measured in a pre-treatment control serum sample.

Claim 68 (Previously Presented) The method of claim 59, wherein said serum titer of the antibodies is measured at a serum dilution of about 1:100.

Claim 69 (Cancelled)

Claim 70 (Currently Amended) The method of claim 11, wherein the subject ~~patient~~ has a known genetic risk of Alzheimer's disease ~~the disorder~~.

Claim 71 (Currently Amended) The method of claim 59, wherein the subject ~~patient~~ has a known genetic risk of Alzheimer's disease ~~the disorder~~.

Claim 72 (New) The method of claim 11, wherein said Aβ fragment is Aβ1-3.

Claim 73 (New) The method of claim 11, wherein said Aβ fragment is Aβ1-4.

Claim 74 (New) The method of claim 11, wherein said Aβ fragment is Aβ1-5.

Claim 75 (New) The method of claim 11, wherein said Aβ fragment is Aβ1-6.

Claim 76 (New) The method of claim 11, wherein said Aβ fragment is Aβ1-7.

Claim 77 (New) The method of claim 11, wherein said Aβ fragment is Aβ3-7.

Claim 78 (New) The method of claim 11, wherein said Aβ fragment is Aβ1-10.

Claim 79 (New) The method of claim 11, wherein said Aβ fragment is Aβ1-12.

Claim 80 (New) The method of claim 11, wherein said Aβ fragment is Aβ13-28.

Claim 81 (New) The method of claim 11, wherein said Aβ fragment is Aβ25-35.

Claim 82 (New) The method of claim 11, wherein said Aβ fragment is Aβ33-42.

Claim 83 (New) The method of claim 11, wherein said Aβ fragment is linked to a carrier molecule to form a conjugate.

Claim 84 (New) The method of claim 72, wherein said Aβ fragment is linked to a carrier molecule to form a conjugate.

Claim 85 (New) The method of claim 73, wherein said Aβ fragment is linked to a carrier molecule to form a conjugate.

Claim 86 (New) The method of claim 74, wherein said Aβ fragment is linked to a carrier molecule to form a conjugate.

Claim 87 (New) The method of claim 75, wherein said Aβ fragment is linked to a carrier molecule to form a conjugate.

Claim 88 (New) The method of claim 76, wherein said Aβ fragment is linked to a carrier molecule to form a conjugate.

Claim 89 (New) The method of claim 77, wherein said Aβ fragment is linked to a carrier molecule to form a conjugate.

Claim 90 (New) The method of claim 78, wherein said Aβ fragment is linked to a carrier molecule to form a conjugate.

Claim 91 (New) The method of claim 79, wherein said Aβ fragment is linked to a carrier molecule to form a conjugate.

Claim 92 (New) The method of claim 80, wherein said Aβ fragment is linked to a carrier molecule to form a conjugate.

Claim 93 (New) The method of claim 81, wherein said Aβ fragment is linked to a carrier molecule to form a conjugate.

Claim 94 (New) The method of claim 82, wherein said Aβ fragment is linked to a carrier molecule to form a conjugate.

Claim 95 (New) The method of claim 59, wherein said Aβ fragment is Aβ1-3.

Claim 96 (New) The method of claim 59, wherein said Aβ fragment is Aβ1-4.

Claim 97 (New) The method of claim 59, wherein said Aβ fragment is Aβ1-5.

Claim 98 (New) The method of claim 59, wherein said Aβ fragment is Aβ1-6.

Claim 99 (New) The method of claim 59, wherein said Aβ fragment is Aβ1-7.

Claim 100 (New) The method of claim 59, wherein said Aβ fragment is Aβ3-7.

Claim 101 (New) The method of claim 59, wherein said Aβ fragment is Aβ1-10.

Claim 102 (New) The method of claim 59, wherein said Aβ fragment is Aβ1-12.

Claim 103 (New) The method of claim 59, wherein said Aβ fragment is Aβ13-28.

Claim 104 (New) The method of claim 59, wherein said Aβ fragment is Aβ25-35.

Claim 105 (New) The method of claim 59, wherein said Aβ fragment is Aβ33-42.

Claim 106 (New) The method of claim 59, wherein said Aβ fragment is linked to a carrier molecule to form a conjugate.

Claim 107 (New) The method of claim 95, wherein said Aβ fragment is linked to a carrier molecule to form a conjugate.

Claim 108 (New) The method of claim 96, wherein said Aβ fragment is linked to a carrier molecule to form a conjugate.

Claim 109 (New) The method of claim 97, wherein said Aβ fragment is linked to a carrier molecule to form a conjugate.

Claim 110 (New) The method of claim 98, wherein said Aβ fragment is linked to a carrier molecule to form a conjugate.

Claim 111 (New) The method of claim 99, wherein said Aβ fragment is linked to a carrier molecule to form a conjugate.

Claim 112 (New) The method of claim 100, wherein said Aβ fragment is linked to a carrier molecule to form a conjugate.

Claim 113 (New) The method of claim 101, wherein said Aβ fragment is linked to a carrier molecule to form a conjugate.

Claim 114 (New) The method of claim 102, wherein said Aβ fragment is linked to a carrier molecule to form a conjugate.

Claim 115 (New) The method of claim 103, wherein said Aβ fragment is linked to a carrier molecule to form a conjugate.

Claim 116 (New) The method of claim 104, wherein said Aβ fragment is linked to a carrier molecule to form a conjugate.

Claim 117 (New) The method of claim 105, wherein said Aβ fragment is linked to a carrier molecule to form a conjugate.

6. Authorization for this examiner's amendment was given in a telephone interview with Rosemaire Celli (Reg. No. 42,397) on 25 February 2004.

7. An extension of time under 37 CFR 1.136(a) is required to place this application in condition for allowance. During a telephone conversation conducted on 25 February 2004, a requested an extension of time for 1 MONTH(S) and authorized the Director to charge Deposit Account No. 20-1430 the required fee of $110.00 for this extension.

Summary

8. Claims 11, 14, 21-25, 59, 60, 64-68, and 70-117 are allowed.

9. The Examiner acknowledges that acceptance of the above Examiner's Amendment does not mitigate in any way, shape, or form, Applicant's right to pursue additional subject matter in continuation, continuation-in-part, and/or divisional applications pursuant to 35 U.S.C. §120 and §121.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on **(571) 272-0887**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

CJN
March 1, 2004

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